



PATENT
Attorney Docket No.: RIB-005

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANTS: Steitz *et al.*
SERIAL NO.: 10/072,634 GROUP NO.: 2683
FILING DATE: February 8, 2002 EXAMINER: Not yet assigned
TITLE: Ribosome Structure and Protein Synthesis Inhibitors

Commissioner for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with the provisions of 37 C.F.R. 1.97 and 1.98, Applicants hereby make of record the patents and publications listed on the accompanying Form PTO-1449, and other information contained herein, for consideration by the Examiner in connection with the examination of the above-identified patent application. Copies of the patents and publications are enclosed.

REMARKS

In accordance with the provisions of 37 C.F.R. 1.97, this statement is being filed (CHECK ONE):

- ☒ (1) within three (3) months of the **filing date** of a national application other than a continued prosecution application under 37 C.F.R. 1.53(d), or within three (3) months of the **date of entry of the national stage** as set forth in 37 C.F.R. 1.491 in an international application, or before the mailing of the **first Office action** on the merits, or before the mailing of a **first Office action** after the filing of a request for continued examination under 37 C.F.R. 1.114; or
- ☐ (2) after the period defined in (1) but before the mailing date of a **final action** or a **notice of allowance** under 37 C.F.R. 1.311, and
- ☐ the requisite Statement is below, **OR**
- ☐ the requisite fee under 37 C.F.R. 1.17(p), namely **\$180.00**, is included herein, or
- ☐ (3) after the mailing date of a **final action** or **notice of allowance** but before the payment of the **issue fee**, **AND**

- ☐ the requisite Statement is below, **AND**
- ☐ the requisite petition fee under 37 C.F.R. 1.17(p), namely **\$180.00** is included herein.

It is respectfully requested that each of the patents and publications listed on the attached Form PTO-1449, and other information contained herein, be made of record in this application.

STATEMENT

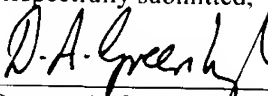
As required under 37 C.F.R. 1.97(e), Applicant(s), through the undersigned, hereby state either that [check the appropriate space only if either (2) or (3) is checked on the previous page and the Statement is required]:

- ☐ 1. Each item of information contained in the Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application **not more than three months** prior to the filing of the Information Disclosure Statement; or
- ☐ 2. No item of information contained in the Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this Statement after making reasonable inquiry, no item of information contained in the Information Disclosure Statement was known to **any individual** designated in 37 C.F.R. 1.56(c) **more than three months** prior to the filing of the Information Disclosure Statement.

Date: September 26, 2002
Reg. No.: 38,678

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Respectfully submitted,



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ATTORNEY DOCKET NO.: RJB-005

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U.S. PATENT DOCUMENTS

EXAM. INIT.	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS

EXAM. INIT.	DOCUMENT NUMBER	DATE	COUNTRY CODE	CLASS	SUB CLASS	FILING DATE	ABSTRACT ONLY	ENGLISH LANG (Y/N)
	B1	EP 1 172 374 A1	01/16/02	EP		07/13/01		Yes
	B2	WO 99/63937 A3	12/16/99	PCT		06/08/99		Yes
	B3	WO 01/80863 A1	11/01/01	PCT		04/27/01		Yes

OTHER ART, JOURNAL ARTICLES, ETC.

EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)							
	C1	Agalarov, S., <i>et al.</i> , (2000) "Structure of the S15, S6, S18-rRNA Complex: Assembly of the 30S Ribosome Central Domain," <u>Science</u> Vol. 288, pp. 107-112						
	C2	Agrawal, R., <i>et al.</i> , (1998) "Visualization of Elongation Factor G on the <i>Escherichia coli</i> 70S Ribosome: The Mechanism of Translocation," <u>Proc. Natl. Acad. Sci. USA</u> Vol. 95, pp. 6134-6138						
	C3	Ban, N., <i>et al.</i> , (2000) "The Complete Atomic Structure of the Large Ribosomal Subunit at 2.4 Å Resolution," <u>Science</u> Vol. 289, No. 5481, pp. 821-1096						
	C4	Ban, N., <i>et al.</i> , (1999) "Placement of Protein and RNA Structures into a 5 Å-Resolution Map of the 50S Ribosomal Subunit," <u>Nature</u> Vol. 400, pp. 841-847						
	C5	Ban, N., <i>et al.</i> , (1998) "A 9 Å Resolution X-Ray Crystallographic Map of the Large Ribosomal Subunit," <u>Cell</u> Vol. 93, pp. 1105-1115						
	C6	Baranov, P., <i>et al.</i> , (1998) "The Database of Ribosomal Cross Links (DRC)," <u>Nucleic Acids Research</u> Vol. 26, No. 1, pp. 187-189						
	C7	Brodersen, D., <i>et al.</i> , (2000) "The Structural Basis for the Action of the Antibiotics Tetracycline, Pactamycin, and Hygromycin B on the 30S Ribosomal Subunit," <u>Cell</u> Vol. 103, pp. 1143-1154						
	C8	Brünger, A., <i>et al.</i> , (1998) "Crystallography & NMR System: A New Software Suite for Macromolecular Structure Determination," <u>Acta Cryst.</u> Vol. D54, pp. 905-921						
	C9	Brünger, A., (1997) "Patterson Correlation Searches and Refinement," <u>Methods in Enzymology</u> , Vol. 276, pp. 558-580						
	C10	Carter, A., <i>et al.</i> , (2001) "Crystal Structure of an Initiation Factor Bound to the 30S Ribosomal Subunit," <u>Science</u> Vol. 291, pp. 498-501						



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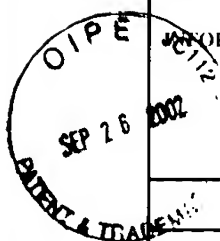
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OTHER ART, JOURNAL ARTICLES, ETC.

EXAM. INTF.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)	
	C11	Carter, A., <i>et al.</i> , (2000) "Functional Insights from the Structure of the 30S Ribosomal Subunit and It's Interactions with Antibiotics," <u>Nature</u> Vol. 407, pp. 340-348
	C12	Cate, J., <i>et al.</i> , (1999) "X-Ray Crystal Structures of 70S Ribosome Functional Complexes," <u>Science</u> Vol. 285, No. 5, pp. 2095-2104
	C13	Clemons, W. Jr., <i>et al.</i> , (1999) "Structure of a Bacterial 30S Ribosomal Subunit at 5.5 Å Resolution," <u>Nature</u> Vol. 400, pp. 833-840
	C14	Culver, G., <i>et al.</i> , (1999) "Identification of an RNA-Protein Bridge Spanning the Ribosomal Subunit Interface," <u>Science</u> Vol. 285, pp. 2133-2135
	C15	Dahlberg, A., <i>et al.</i> , (2001) "The Ribosome in Action," <u>Science</u> Vol. 292, pp. 868-869
	C16	Davies, C., <i>et al.</i> , (1998) "Ribosomal Proteins S5 and L16: High-Resolution Crystal Structures and Roles in Protein Synthesis and Antibiotic Resistance," <u>Journal of Molecular Biology</u> , Vol. 279, pp. 873-888
	C17	Di Giambattista, M., <i>et al.</i> , (1990) "Affinity Labeling of the Virginiamycin S ₁ Binding Site on Bacterial Ribosome," <u>Biochemistry</u> Vol. 29, pp. 9203-9211
	C18	Douthwaite, S., <i>et al.</i> , (1995) "Recognition Determinants for Proteins and Antibiotics within 23S rRNA," <u>Biochem. Cell Biol.</u> Vol. 73, pp. 1179-1185
	C19	Douthwaite, S., <i>et al.</i> , (1993) "Erythromycin Binding is Reduced in Ribosomes with Conformational Alterations in the 23 S rRNA Peptidyl Transferase Loop," <u>Journal Mol. Biol.</u> Vol. 232, pp. 725-731
	C20	Douthwaite, (1992) "Functional Interactions within 23S rRNA Involving the Peptidyltransferase Center," <u>Journal of Bacteriology</u> Vol. 174, No. 4, pp. 1333-1338
	C21	Fitzhugh, A., <i>et al.</i> , (1998) "Antibiotic Inhibitors of the Peptidyl Transferase Center. 1. Clindamycin as a Composite Analogue of the Transfer RNA Fragments L-Pro-Met and the D-Ribosyl Ring of Adenosine," <u>Bioorganic and Medicinal Chemistry Letters</u> , Vol. 8, pp. 87-92
	C22	Gabashvili, I., <i>et al.</i> , (2000) "Solution Structure of the <i>E. coli</i> 70S Ribosome at 11.5 Å Resolution," <u>Cell</u> , Vol. 100, pp. 537-549
	C23	Garrett, R., <i>et al.</i> , (1996) "The Peptidyl Transferase Center," <u>Ribosomal RNA</u> pp. 327-355
	C24	Garza-Ramos, G., <i>et al.</i> , (2001) "Binding Site of Macrolide Antibiotics on the Ribosome: New Resistance Mutation Identifies a Specific Interaction of Ketolides with rRNA," <u>Journal of Bacteriology</u> , Vol. 183, No. 23, pp. 6898-6907
	C25	Gonzales, R., <i>et al.</i> , (2001) "Infections Due to Vancomycin-Resistant <i>Enterococcus faecium</i> Resistant to linezolid," <u>The Lancet</u> Vol. 357, p. 1179
	C26	Green, R., <i>et al.</i> , (1997) "Ribosomes and Translation," <u>Annu. Rev. Biochemistry</u> Vol. 66, pp. 679-716



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	C27	Gregory, S., <i>et al.</i> , (1999) "Erythromycin Resistance Mutations in Ribosomal Proteins L22 and L4 Perturb the Higher Order Structure of 23 S Ribosomal RNA," <u>J. Mol. Biol.</u> Vol. 289, pp. 827-834
	C28	Gschwend, D. <i>et al.</i> , (1996) "Molecular Docking Towards Drug Discovery," <u>Journal of Molecular Recognition</u> , Vol. 9, pp. 175-186
	C29	Guetell, R. (1996) "Comparative Sequence Analysis and the Structure of 16S and 23S rRNA," <u>Ribosomal RNA</u> pp. 111-128
	C30	Hansen, H.A.S., <i>et al.</i> , (1990) "Crystals of Complexes Mimicking Protein Biosynthesis are Suitable for Crystallographic Studies," <u>Biochimica et Biophysica Acta</u> Vol. 1050, pp. 1-7
	C31	Harms, J., <i>et al.</i> , (2001) "High Resolution Structure of the Large Ribosomal Subunit from a Mesophilic Eubacterium," <u>Cell</u> , Vol. 107, pp. 679-688
	C32	Harms, J., <i>et al.</i> , (1999) "Elucidating the Medium-Resolution Structure of Ribosomal Particles: an Interplay between Electron Cryo-Microscopy and X-ray Crystallography," <u>Structure</u> Vol. 7, No. 8, pp. 931-941
	C33	Hansen, L., <i>et al.</i> , (1999) "The Macrolide-Ketolide Antibiotic Binding Site is Formed by Structures in Domains II and V of 23S Ribosomal RNA," <u>Molecular Microbiology</u> , Vol. 31, No. 2, pp. 623-631
	C34	Kloss, P., <i>et al.</i> , (1999) "Resistance Mutations in 23 S rRNA Identify the Site of Action of the Protein Synthesis Inhibitor Linezolid in the Ribosomal Peptidyl Transferase Center," <u>J. Mol. Biol.</u> Vol. 294, No. 1, pp. 93-101
	C35	Lázaro, E., <i>et al.</i> , (1996) "A Sparsomycin-Resistant Mutant of <i>Halobacterium salinarum</i> Lacks a Modification at Nucleotide U2603 in the Peptidyl Transferase Centre of 23 S rRNA," <u>J. Mol. Biol.</u> Vol. 261, No. 2, pp. 231-238
	C36	Lázaro, E., <i>et al.</i> , (1991) "Chemical, Biochemical and Genetic Endeavors Characterizing the Interaction of Sparsomycin with the Ribosome," <u>Biochimie</u> Vol. 73, pp. 1137-1143
	C37	Lipinski, C., <i>et al.</i> , (1997) "Experimental and Computational Approaches to Estimate Solubility and Permeability in Drug Discovery and Development Settings," <u>Adv. Drug Delivery Rev.</u> Vol. 23, No. 3-25
	C38	Maskowski <i>et al.</i> , (1987) "Single Crystals of Large Ribosomal Particles from <i>Halobacterium marismortui</i> Diffract to 6 Å," <u>Journal Molecular Biology</u> Vol. 193 pp. 818-822
	C39	Matadeen, R., <i>et al.</i> , (1999) "The <i>Escherichia Coli</i> Large Ribosomal Subunit at 7.5 Å Resolution," <u>Structure</u> , Vol. 7, No. 12, pp. 1575-1583
	C40	Moazed <i>et al.</i> , (1989) "Interaction of +rRNA with 23S rRNA in the Ribosomal A, P, and E Sites," <u>Cell</u> Vol. 57, pp. 585-597
	C41	Moazed, D., <i>et al.</i> , (1987) "Chloramphenicol, Erythromycin, Carbomycin and Vernamycin B Protect Overlapping Sites in the Peptidyl Transferase Region of 23S Ribosomal RNA," <u>Biochimie</u> Vol. 69, pp. 879-884

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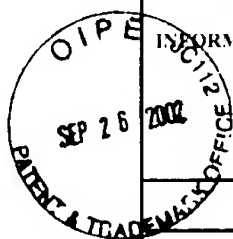
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C42	Moore, P.B. (1999) "Structural Motifs in RNA," <u>Annu. Rev. Biochemistry</u> Vol. 67, pp. 287-300
C43	Moore, P.B. (1998) "The Three-Dimensional Structure of the Ribosome and its Components," <u>Annu. Rev. Biophys.</u> Vol. 27, pp. 35-58
C44	Mueller, F., <i>et al.</i> , (2000) "The 3D Arrangement of the 23 S and 5 S rRNA in the <i>Escherichia coli</i> 50 S Ribosomal Subunit Based on a Cryo-Electron Microscopic Reconstruction at 7.5 Å Resolution," <u>J. Mol. Biol.</u> Vol. 298, pp. 35-59
C45	Mussig, J., <i>et al.</i> , (1989) "Crystals of Wild-type, Mutated, Derivatized and Complexed 50 S Ribosomal Subunits from <i>Bacillus stearotherophilus</i> Suitable for X-ray Analysis," <u>J. Mol. Biol.</u> Vol. 205, pp. 619-621
C46	Nakatogawa, H., <i>et al.</i> , (2002) "The Ribosomal Exit Tunnel Functions as a Discriminating Gate," <u>Cell</u> Vol. 108, pp. 629-636
C47	Navaza, J., <i>et al.</i> , (1997) "AMoRe: An Automated Molecular Replacement Program Package," <u>Methods in Enzymology</u> Vol. 276, pp. 581-595
C48	Nissen, P., <i>et al.</i> , (2000) "The Structural Basis of Ribosome Activity in Peptide Bond Synthesis," <u>Science</u> Vol. 289, pp. 920-930
C49	Nitta, I., <i>et al.</i> , (1998) "Reconstitution of Peptide Bond Formation with <i>Escherichia coli</i> 23S Ribosomal RNA Domains," <u>Science</u> Vol. 281, pp. 666-669
C50	Noller, H., (1991) "Ribosomal RNA and Translation," <u>Ann. Rev. Biochemistry</u> Vol. 60, pp. 191-227
C51	Ogle, J., <i>et al.</i> , (2001) "Recognition of Cognate Transfer RNA by the 30S Ribosomal Subunit," <u>Science</u> Vol. 292, pp. 897-902
C52	Pestka, S., (1974) "Antibiotics as Probes of Ribosome Structure: Binding of Chloramphenicol and Erythromycin to Polyribosomes; Effect of Other Antibiotics," <u>Antimicrobial Agents and Chemotherapy</u> Vol. 5, No. 3, pp. 255-267
C53	Porse, B., <i>et al.</i> , (1999) "Ribosomal Mechanics, Antibiotics, and GTP Hydrolysis," <u>Cell</u> Vol. 97, pp. 423-426
C54	Porse, B., <i>et al.</i> , (1999) "Sites of Interaction of Streptogramin A and B Antibiotics in the Peptidyl Transferase Loop of 23 S rRNA and the Synergism of Their Inhibitory Mechanisms," <u>J. Mol. Biol.</u> Vol 286, No. 2, pp. 375-387
C55	Ramakrishnan, V., (2002) "Ribosome Structure and the Mechanism of Translation," <u>Cell</u> Vol. 108, pp. 557-572
C56	Ramakrishnan, V., <i>et al.</i> , (1995) "Structures of Prokaryotic Ribosomal Proteins: Implications for RNA Binding and Evolution," <u>Biochem. Cell Biol.</u> Vol. 73, pp. 979-986



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EXAM. INIT.	OTHER DOCUMENTS: (Including Author, Title, Date, Relevant Pages, Place of Publication)	
	C57	Rodriguez-Fonseca, C., <i>et al.</i> , (1995) "Fine Structure of the Peptidyl Transferase Centre on 23 S-like rRNAs Deduced from Chemical Probing of Antibiotic-Ribosome Complexes," <u>J. Mol. Biol.</u> Vol. 247, pp. 224-235
	C58	Schlünzen, F., <i>et al.</i> , (2001) "Structural Basis for the Interaction of Antibiotics with the Peptidyl Transferase Centre in Eubacteria," <u>Nature</u> Vol. 413, pp. 814-821
	C59	Schlünzen, F., <i>et al.</i> , (2000) "Structure of Functionally Activated Small Ribosomal Subunit at 3.3 Å Resolution," <u>Cell</u> Vol. 102, pp. 615-623
	C60	Schlünzen, F., <i>et al.</i> , (1995) "A Milestone in Ribosomal Crystallography: The Construction of Preliminary Electron Density Maps at Intermediate Resolution," <u>Biochemistry Cell Biology</u> Vol. 73, pp. 739-749
	C61	Shinabarger, D., <i>et al.</i> , (1997) "Mechanism of Action of Oxazolidinones: Effects of Linezolid and Eperezolid on Translation Reactions," <u>Antimicrobial Agents and Chemotherapy</u> Vol. 41, No. 10, pp. 2132-2136
	C62	Spahn, C.M.T., <i>et al.</i> , "Throwing a Spanner in the Works: Antibiotics and the Translation Apparatus," <u>Journal of Molecular Medicine</u> , Vol. 74, No. 8, pp. 423-439
	C63	Swaney, S., <i>et al.</i> , (1998) "The Oxazolidinone Linezolid Inhibits Initiation of Protein Synthesis in Bacteria," <u>Antimicrobial Agents and Chemotherapy</u> Vol. 42, No. 12, pp. 3251-3255
	C64	Tenson, T., <i>et al.</i> , (2002) "Regulatory Nascent Peptides in the Ribosomal Tunnel," <u>Cell</u> Vol. 108, pp. 591-594
	C65	Timmermans, P., <i>et al.</i> , (1982) "Sparsopencicol: A New Synthetic Hybrid Antibiotic Inhibiting Ribosomal Peptide Synthesis" <u>J. Med. Chem.</u> Vol. 25, pp. 1123-1125
	C66	Tocij, A., <i>et al.</i> , (1999) "The Small Ribosomal Subunit from <i>Thermus Thermophilus</i> at 4.5 Å Resolution: Pattern Fittings and the Identification of a Functional Site," <u>Proc. Natl. Acad. Sci. USA</u> Vol. 96, pp. 14252-14257
	C67	Trakhanov, S.D., <i>et al.</i> , (1987) "Crystallization of 70 S Ribosomes and 30 S Ribosomal Subunits from <i>Thermus thermophilus</i> ," <u>Febs Letters</u> , Vol. 220, No. 2, pp. 319-322
	C68	Tronrud, D., (1997) "TNT Refinement Package," <u>Macromolecular Crystallography, Part B, Methods in Enzymology</u> Vol. 277, pp. 306-319
	C69	Tsiodras, S., <i>et al.</i> , (2001) "Linezolid Resistance in a Clinical Isolate of <i>Staphylococcus Aureus</i> ," <u>The Lancet</u> Vol. 358, pp. 207-208
	C70	Vannuffel <i>et al.</i> , (1996) "Mechanism of Action of Streptogramins and Macrolides," <u>Drugs</u> Vol. 51, Suppl 1, pp. 20-30
	C71	Vannuffel <i>et al.</i> , (1992) "Identification of a Single Base Change in Ribosomal RNA Leading to Erythromycin Resistance," <u>J. Biol. Chem.</u> Vol. 267(12), pp. 8377-8382



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| C72 | Vester <i>et al.</i> , (2001) "Macrolide Resistance Conferred by Base Substitutions," <u>Antimicrobial Agents and Chemotherapy</u> Vol. 45, No. 1, pp. 1-12 |
| C73 | Vester <i>et al.</i> , (1988) "The Importance of Highly Conserved Nucleotides in the Binding Region of Chloramphenicol at the Peptidyl transfer Centre of <i>Escherichia coli</i> 23S Ribosomal RNA," <u>The EMBO Journal</u> Vol. 7, No. 11, pp. 3577-3587 |
| C74 | Volkman <i>et al.</i> , (1990) "Characterization and Preliminary Crystallographic Studies on Large Ribosomal Subunits from <i>Thermus thermophilus</i> ," <u>J. Mol. Biol.</u> Vol. 216, pp. 239-241 |
| C75 | Von Bohlen (1991) "Characterization and Preliminary Attempts for Derivatization of Crystals of Large Ribosomal Subunits from <i>Haloarcula marismortui</i> Diffracting to 3 Å Resolution," <u>J. Mol. Biol.</u> Vol. 222, pp. 11-15 |
| C76 | Welch, M., <i>et al.</i> , (1997) "23S rRNA Similarity from Selection for Peptidyl Transferase Mimicry," <u>Biochemistry</u> Vol. 36, pp. 6614-6623 |
| C77 | Welch, M., <i>et al.</i> , (1995) "An Inhibitor of Ribosomal Peptidyl Transferase Using Transition-State Analogy," <u>Biochemistry</u> Vol. 34, pp. 385-390 |
| C78 | Wimberly, B., <i>et al.</i> , (2000) "Structure of the 30S Ribosomal Subunit," <u>Nature</u> Vol. 407, pp. 327-339 |
| C79 | Wittmann <i>et al.</i> , (1982) "Crystallization of <i>Escherichia coli</i> Ribosomes," <u>Febs Letters</u> Vol. 146, No. 1, pp. 217-220 |
| C80 | Wool, I., <i>et al.</i> , (1995) "Structure and Evolution of Mammalian Ribosomal Proteins," <u>Biochemistry Cell Biology</u> Vol. 73, pp. 933-947 |
| C81 | Xiong, L., <i>et al.</i> , (2000) "Oxazolidinone Resistance Mutations in 23S rRNA of <i>Escherichia coli</i> Reveal the Central Region of Domain V as the Primary Site of Drug Action," <u>Journal of Bacteriology</u> Vol. 182, No. 19, pp. 5325-5331 |
| C82 | Yonath, A., <i>et al.</i> , (1998) "Crystallographic Studies on the Ribosome, a Large Macromolecular Assembly Exhibiting Severe Nonisomorphism, Extreme Beam Sensitivity and No Internal Symmetry," <u>Acta Cryst.</u> Vol. A54, pp. 945-955 |
| C83 | Yonath, A., <i>et al.</i> , (1986) "Characterization of Single Crystals of the Large Ribosomal Particles from <i>Bacillus stearothermophilus</i> ," <u>J. Mol. Biol.</u> Vol. 187, pp. 633-636 |
| C84 | Yusupov, G., <i>et al.</i> , (2001) "The Path of Messenger RNA through the Ribosome," <u>Cell</u> Vol. 106, pp. 233-241 |
| C85 | Yusupov, M., <i>et al.</i> , (2001) "Crystal Structure of the Ribosome 5.5 Å Resolution," <u>Science</u> Vol. 292, pp. 883-896 |
| C86 | Yusupov, M., <i>et al.</i> , (1991) " <i>Thermus thermophilus</i> Ribosomes for Crystallographic Studies," <u>Biochimie</u> Vol. 73, pp. 887-897 |
| C87 | Zemlicka, J., <i>et al.</i> , (1993) "Hybrids of Antibiotics Inhibiting Protein Synthesis. Synthesis and Biological Activity," <u>J. Med. Chem.</u> Vol. 36, pp. 1239-1244 |
| C88 | European Search Report for Application No. 01306825.9 dated May 24, 2002 |